K022502
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510(k) Summary
(As required by 21 CFR 807.92(a))

A. Submitter Information

Equidyne Systems Inc.
11770 Bernardo Plaza Court, Suite 351
San Diego, CA 92128

Phone Number: 858-451-7001
Fax Number: 858-451-7002
Contact: Jim Barley
Regulatory Affairs
Date: July 26, 2002

B. Device Information

Trade/Proprietary Name:	Injex 30 Needle Free Insulin Injector System
Common name of device:	Jet Injector
Classification Name:	Injector, Fluid, Non-Electrically Powered

C: Predicate Device: Medi Ject Choice Insulin Delivery System

Predicate 510(k) #: K991294

D. Device Description:

Equidyne Systems Injex 30 Needle Free Insulin Injector System is a means of administering insulin in the subcutaneous tissue without the use of needles. The needle free injector utilizes a high velocity focused jet of liquid to penetrate the skin and deposit the insulin in the subcutaneous tissue. The process takes place in a fraction of a second.

D. Device Description: (cont.)

The Injex 30 Needle-Free Insulin Injector System consists of four main components;

1. Injex 30 Needle-Free Insulin Injector - A small re-usable hand held Injector,
2. Reset Box - A compact re-usable Reset Box used to reset the Injex 30 Needle Free Insulin Injector,
3. Injex 30 Insulin Ampule - A disposable, sterile 30 unit Injex 30 Insulin Ampule that functions like a needle syringe to draw the medication from the medicine bottle or vial using a hand draw with a plunger. Once the Injex 30 Insulin Ampule is loaded into the Injex 30 Needle Free Insulin Injector, the dose is injected into the individual by releasing the Safety and pressing the trigger.
4. Vial Adapter - A disposable, sterile Vial Adapter facilitates the transfer of the insulin from the medicine bottle or vial to the Injex 30 Insulin Ampule.

The Injex 30 Needle Free Insulin Injector can deliver variable doses of insulin from 5 to 30 units. The Injex 30 Insulin Ampule scale is in 1 unit increments.

E. Intended Use:

The over the counter Injex 30 Needle-Free Insulin Injector System is intended for the subcutaneous injection of U-100 insulin. The Injex 30 Insulin Ampule is labeled as suitable for administration of 5 to 30 insulin units with a scale in 1 unit increments.

F. Comparison of Required Technological Characteristics:

This submission changes the labeling and design of the Injex 30 Needle Free Injector System, 510(k) number K022148 to allow the device to be sold over the counter for insulin use. The Injex 30 Needle Free Insulin Injector System has the same technological characteristics as the Medi-Ject Choice Insulin Delivery System.

G. Summary and Conclusion of Nonclinical and Clinical Tests:

A clinical study was conducted to determine if the labeling and Instructions for Use for the Injex System are adequate instruction for an individual to administer an injection using the Injex family of injectors and to determine if the ease of use and pain using the Injex family of injectors are substantially equivalent to that of a needle and syringe.

Study Results

There was a good distribution of age among the subjects with the average age being 48.5 years with a range of 25 to 77 years old.

Subject education was representative of the public with 18% of the subjects having an eighth grade education or less and 82% of the subjects had a high school education or less. Eighteen percent of the subjects had more than a high school education.

After injecting themselves using the Injex 30 Needle-Free Insulin Injector System and an insulin needle and syringe, subjects were given a Labeling and Substantial Equivalence Questionnaires.

Results from the questionnaire include:

100% of the subjects said that it was either easy or somewhat easy to give themselves an injection after viewing the training video and reading the Instructions for Use. None of the subjects said that it was difficult or they were not able to give themselves an injection after viewing the training video and reading the Instructions for Use.

84% of the subjects said that they either prefer the Injex 30 Needle-Free Insulin Injector or would use either the Injex 30 Needle-Free Insulin Injector or a needle and syringe in the future.

91% of the subjects said the pain from the Injex 30 Needle-Free Insulin Injector was either the same as, a little less or a lot less than the insulin needle and syringe.

91% of the subjects felt that the Injex 30 Needle-Free Insulin Injector was just as easy to use as an insulin needle and syringe.

100% of the subjects felt it was just as easy to give themselves an injection using the Injex 30 Needle-Free Insulin Injector as it was with a insulin needle and syringe.

Clinical Study Conclusion

The results of this clinical study show that the Injex labeling and instructions for use are adequate for an individual to give themselves an insulin injection using the family of Injex Injectors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 5 2002

Mr. Jim Barely
Equidyne Systems, Incorporated
11770 Bernardo Plaza Court, Suite 351
San Diego, California 92128

Re: K022502
Trade/Device Name: Injex 30 Needle Free Injection System
Regulation Number: 880.5430
Regulation Name:
Regulatory Class: II
Product Code: KZE
Dated: July 26, 2002
Received: July 29, 2002

Dear Mr. Barely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Injex 30 Needle Free Insulin Injector System

Indications for Use:

The over the counter Injex 30 Needle-Free Insulin Injection System is intended for the subcutaneous injection of U-100 insulin. The Ampule is labeled as suitable for administration of 5 to 30 insulin units in 1 unit increments.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K022502